MAR - 5 2012

510(k) Summary: Prepared on March 1, 2012

Company:
Eisertech, LLC
2555 Front Street
San Diego, California 92103

Contact:
Lukas Eisermann
lukas@eisertech.com
888-262-2817x101

Trade Name: PLIF Cage

Common Name: Intervertebral FusionDevice with Bone Graft, Lumbar

Classification Name: Orthosis, spinal intervertebral fusion

Regulation Number: 888.3080

Product Code: MAX

Substantial Equivalence

Eisertech, LLC believes that the Eisertech, LLC PLIF Cage is substantially equivalent to the Aesculap ProSpace PEEK Spinal Implant System (k071983), the Medtronic Sofamor Danek CAPSTONE Spinal System (k073291), and the Synthes Oracle and Opal Spacer (k072791).

Device Description

The PLIF Cage is a hollow, generally rectangular box made of polyetheretherketone (PEEK) and having titanium x-ray markers. It is provided in a variety of shapes and sizes, and is intended to be filled with a bone graft material. The smallest footprint of the device is 8mm medial-lateral x 20mm anterior-posterior. The largest footprint is 12mm medial-lateral x 30mm anterior-posterior. Available heights range from 7mm to 16mm. The device is available either in a non-lordosed configuration, or with a built-in six degree lordotic angle.

The PLIF cage may be inserted via an open or minimally invasive approach. It may be placed singly or in pairs.

Bone graft volume of the device is variable depending on the device size; larger sizes have more volume for graft. The smallest graft volume, in the 20x8x7mm non-lordotic device is approximately 354.1mm^3 (0.4cc), while the largest in the 30x12x16 lordotic device is approximately 3,530mm^3 (3.5cc).

The surface area of the device contacting the endplates ranges from 118mm^2 to 220mm^2 for the smallest and largest footprint devices, respectively.

The PLIF cage may be made either from Zeniva PEEK (Solvay Advanced Polymers, Alpharetta, GA USA) or PEEK Optima (Invibio, Inc., West Conshohocken, PA USA). The particular grade of PEEK used is tracked via product lot numbering and is displayed on the package label.

Indications for Use

The PLIF Cage is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended for intervertebral body fusion, and are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

Description of device design requirements

The PLIF Cage design must maintain the spacing between two vertebral bones following discectomy until fusion occurs.

Identification of the risk analysis method

Risks were qualitatively summarized and addressed by quantitatively analyzing specific in-vivo device performance requirements. The biomechanical loads that the device is expected to be subjected to were described and used as design input criteria. Test results relative to those loading conditions (e.g. design output data) were compared to the design input criteria. The device output data showed performance meeting or exceeding the design input requirements for all conditions.

Discussion of the device characteristics

The PLIF Cage is an intervertebral body fusion orthosis intended to be used in lumbar spinal fusion surgery. It provides mechanical support to the spine and protects the bone graft from excessive loads so that bone healing can occur.

Description of the performance aspects

The PLIF Cage was tested by the methods described in ASTM F2077, including static axial compression, dynamic axial compression, static shear, and dynamic shear. Testing per ASTM F2267 to quantify the potential for device subsidence was also conducted. The resistance to expulsion was evaluated by performing expulsion testing against grade 15 polyurethane foam with 500 N axial preload.

Reliance on standards

Standards relevant to the methods in which the testing was conducted were relied upon. These include ASTM F2077 and ASTM F2267. However, no

performance standard exists for intervertebral body fusion orthoses.

Comparison to predicate devices
Mechanical testing has demonstrated that the PLIF Cage is equivalent in function to the following predicate devices:

Aesculap ProSpace PEEK Spinal Implant System (k071983),
the Medtronic Sofamor Danek CAPSTONE Spinal System (k073291), and
the Synthes Oracle and Opal Spacer (k072791).

Each device performs the same mechanical function, holding open the disc space while a bone graft located inside the device fuses.

The devices are made of the same materials, and have similar shapes and sizes.

Non-clinical testing has demonstrated equivalence of the Eisertech PLIF Cage with the above-referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Eisertech, LLC
% Mr. Lukas Eisermann
CEO
2555 Front Street
San Diego, California 92103

MAR - 5 2012

Re: K113478
Trade/Device Name: PLIF Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: January 13, 2012
Received: January 23, 2012

Dear Mr. Eisermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): k113478.

Device Name: PLIF Cage

Indications for Use:

The PLIF Cage is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended for intervertebral body fusion, and are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113478